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EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/516,789	FUCHS ET AL.	
	Examiner	Art Unit	
	Amy L. Clark	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *09/06/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group II, Claims 25-30 and Applicant's cancellation of claims 14-24 and addition of new claims 31-35 in the reply filed on 16 October 2006 is acknowledged.

Claims 25-35 are currently pending.

Claims 25-35 are under examination.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 22 August 2005 was filed after the mailing date of the claims, specification and abstract on 22 October 2004. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Please note that the Examiner did not consider Reference B1 (EP 0 770 324), Reference B2 (EP 0 799 578) and Reference C1 (Fuches et al.) nor did the Examiner consider the entire reference C2 (please note the Examiner only considered the Abstract because it was the only part of the document translated into English) because Applicant did not provide English translations of these reference.

Specification

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract of the disclosure is objected to because the abstract is more than one paragraph. Correction is required. See MPEP § 608.01(b).

The specification is objected to because the specification recites, "The invention relates to novel uses of agents prepared from seedlings enriched with electrolytes" on page 1, lines 1 and 2 and on page 2 (bottom of the page). It is suggested that the term "novel" be deleted from the language of the specification. Once the determination of the novelty of a claimed invention has been established and the disclosure of the invention made public and/or patented, the claimed invention is no longer novel, since the scope of the invention no longer embraces what is considered "novel". Thus, the incorporation of "novel" into the language of the specification is not appropriate. Appropriate correction is required. See MPEP § 608.01(b).

The use of the trademark PMN® and of trademark ISF® has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 25-35 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a "written description" rejection, rather than an enablement rejection under 35 U.S.C. 112, first paragraph. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, & 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Vas-Cath Inc. V. Mahurka, 19 USPQ2d 1111, states that applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention, for purposes of the "written

description" inquiry, is "*whatever is now claimed*" (See page 1117).

A review of the language of the claim indicates that these claims are drawn to a method comprising: obtaining an agent prepared from plant seedlings enriched with electrolytes comprised in a pharmaceutical preparation; and administering the preparation to a person; wherein administration of the preparation results in reduction of blood cholesterol concentration in the person.

A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In *Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that, while applicants are not required to disclose every species encompassed by a genus, the description of the genus is achieved by the recitation of a representative number of species falling within the scope of the claimed genus. At section B (1), the court states "An adequate written description of a DNA ... requires a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention". Hence, an adequate written description of the ingredients requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it.

The description requirement of the patent statue requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736 F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984). Accordingly, describing a method comprising: obtaining an agent prepared from plant seedlings enriched with electrolytes comprised in a pharmaceutical preparation; and administering the preparation to a person; wherein administration of the preparation results in reduction of blood cholesterol concentration in the person, in the absence of knowledge as to what the material consists of or the source of the material is not a description of the material. In the instant case, on pages 2 and 3 of the specification, Applicant discloses that "The object of the present invention, therefore, resides in the use of an agent prepared from plant seedlings enriched with electrolytes for the production of a pharmaceutical preparation aimed to proliferate T-lymphocytes in non-immune-suppressed persons. It was shown in a surprising manner that said agents were able to provide positive effects not only in immune-suppressed persons having pathologic values in respect to their cellular immune systems, but also in non-immune suppressed persons. In the context of the present invention it was, however, demonstrated that--unlike with the treatment of immune-suppressed individuals, which goes hand in hand with an increase in the quotient from T helper cells and T suppressor cells (cf. EP 0 799 578 A)--that quotient in non-immune-suppressed individuals develops into the opposite direction, that is to say rather towards T suppressor cells", "It was, furthermore, shown that the agents prepared from plant seedlings enriched with electrolytes according to the invention could also be used for the production of a

pharmaceutical preparation aimed to lower cholesterol concentration in blood (i.e., induce reduced cholesterol concentration in blood)" on page 3, and "Furthermore, agents of this type are suitable for the production of a pharmaceutical preparation aimed to reduce low-density lipoprotein (LDL) concentration in blood (i.e., to induce reduced LDL concentration in blood" also on page 3 of the specification. However, other than a vague description of what occurs during a conventional method of seed germination, wherein Applicant simply states, "Conventional seed germination, in which the seeds are placed in distilled water or tap water for germination, always involves partially considerable losses of such nutritionally relevant components. Those losses were due both to the beginning metabolic process of the plant seedling itself and to the nature of the swelling agent water, which caused additional electrolyte leaching of the seedling, since, unlike in the resting state (seed), the husk of the seedling is, in fact, susceptible to electrolyte leaching" on page 5, and an vague description of patient collective on pages 9 and10, wherein Applicant states, "The average patient age was 85 years (62-98) in the verum group and 85.5 years (65-98) in the placebo group. The age and sex distribution corresponds to demographic studies of this age population. These distribution patterns do not significantly change in respect to the patients defined for the "per protocol analysis" as far as age and sex are concerned. Patients having consumed at least 50% of the test agent for at least 80% of the days of therapy were defined as such. The verum group, thus, included 40 (32 female and 8 male) and the placebo group 42 (35 female and 7 male) persons", and Applicant discloses The specification describes a test medication based on dried electrolyte-enriched seedlings, particularly

wheat seedlings, having high concentrations of endogenous vitamins, essential fatty acids and trace element complexes, a dietary food PMN® (Pan Molecular Nutrients) micronutrient concentrate was used in the context of the present trial ("immunostabilizing factor") ISF® versus placebo, which was administered daily over three months in soup form (dissolved in hot water) (See page 8 of the specification) (Emphasis added by the Examiner). The specification further describes phenotyping lymphocytes by FACS, testing of lymphocyte function (IL-2, IL-2R) and lymphocyte activatability *in vitro*, antibody titer after influenza vaccination, and clinical parameters/registration of undesired effects (See pages 8-21 of the specification), however, Applicant fails to adequately describe as to what Applicant defines or considers as "an agent prepared from plant seedlings enriched with electrolytes" and Applicant does not disclose what exactly Applicant intends as the composition for providing all the effects claimed in claims 25-28 and 31-35. For example, nowhere in the present specification does Applicant render a definition of the term "an agent prepared from plant seedlings" nor does Applicant render a definition of the term "an agent" nor does Applicant provide any sort of explanation of what PMN® (Pan Molecular Nutrients) contains or what ("immunostabilizing factor") ISF® contains or what both of the trademarked ingredients (please note that the Examiner is unsure of what PMN® and ISF® are and is not quite sure if they are ingredients, but is merely guessing that they are) are nor does Applicant cite an example of these terms thereof.

One of skill in the art would not recognize from the disclosure that the applicant was in possession of the genus of what constitutes "a method comprising: obtaining an

agent prepared from plant seedlings enriched with electrolytes comprised in a pharmaceutical preparation; and administering the preparation to a person; wherein administration of the preparation results in reduction of blood cholesterol concentration in the person". The specification does not clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed (see *Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

Claims 25-35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Enablement is considered in view of the *Wands* factors (MPEP 2164.O1(A)). These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of working examples, state of the art predictability of the art and the amount of experimentation necessary. All of the Wands factors have been considered with regard to the instant claims, with the most relevant factors discussed below.

Nature of the Invention: The claims are drawn to a method comprising: obtaining an agent prepared from plant seedlings enriched with electrolytes comprised in a pharmaceutical preparation; and administering the preparation to a person; wherein administration of the preparation results in reduction of blood cholesterol concentration

in the person, wherein administration of the preparation results in the reduction of low-density lipoprotein (LDL) concentration in the person, wherein administration of the preparation results in a reduced probability of atherosclerosis, wherein administration of the preparation results in proliferation of T-lymphocytes in the person, wherein the preparation results in proliferation of CD3+-specific immune cells in the person, wherein administration of the preparation results in the proliferation of CD3+/CD4+-specific immune cells (helper cells) in the person, wherein administration of the preparation results in proliferation of CD3-/CD16,56+-specific immune cells (natural killer cells) in the person, wherein administration of the preparation results in proliferation of CD4+/CD8+-specific immune cells (suppressor cells) in the person (Claims 25-28 and 31-35).

Breadth of the Claims: The claims are broad in that an agent prepared from plant seedlings enriched with electrolytes may be administered to reduce blood cholesterol concentration in the person, to reduce low-density lipoprotein (LDL) concentration, to reduce the probability of atherosclerosis, wherein administration of the preparation results in proliferation of T-lymphocytes in the person, wherein administration of the preparation results in proliferation of CD3+-specific immune cells in the person, wherein administration of the preparation results in the proliferation of CD3+/CD4+-specific immune cells (helper cells, wherein administration of the preparation results in proliferation of CD3-/CD16,56+-specific immune cells (natural killer cells), and wherein administration of the preparation results in proliferation of CD4+/CD8+-specific immune

cells in a patient. The complex nature of the subject matter of this invention is greatly exacerbated by the breadth of the claims.

Guidance of the Specification and Existence of Working Examples: The specification describes a test medication based on dried electrolyte-enriched seedlings, particularly wheat seedlings, having high concentrations of endogenous vitamins, essential fatty acids and trace element complexes, a dietary food PMN® (Pan Molecular Nutrients) micronutrient concentrate was used in the context of the present trial ("immunostabilizing factor") ISF® versus placebo, which was administered daily over three months in soup form (dissolved in hot water) (See page 8 of the specification) (Emphasis added by the Examiner). The specification further describes phenotyping lymphocytes by FACS, testing of lymphocyte function (IL-2, IL-2R) and lymphocyte activatability *in vitro*, antibody titer after influenza vaccination, and clinical parameters/registration of undesired effects (See pages 8-21 of the specification).

The specification envisions that any agent prepared from any type of plant seedlings enriched with electrolytes will have utility in humans to reduce blood cholesterol concentration in the person, to reduce low-density lipoprotein (LDL) concentration, to reduce the probability of atherosclerosis, wherein administration of the preparation results in proliferation of T-lymphocytes in the person, wherein administration of the preparation results in proliferation of CD3+-specific immune cells in the person, wherein administration of the preparation results in the proliferation of CD3+/CD4+-specific immune cells (helper cells, wherein administration of the preparation results in proliferation of CD3-/CD16,56+-specific immune cells (natural

killer cells), and wherein administration of the preparation results in proliferation of CD4+/CD8+-specific immune cells.

However, no working examples are provided with regard to a method comprising: obtaining any or all types of agents prepared from any or all types of plant seedlings enriched with electrolytes comprised in a pharmaceutical preparation; and administering the preparation to a person; wherein administration of the preparation results in reduction of blood cholesterol concentration in the person, wherein administration of the preparation results in the reduction of low-density lipoprotein (LDL) concentration in the person, wherein administration of the preparation results in a reduced probability of atherosclerosis, wherein administration of the preparation results in proliferation of T-lymphocytes in the person, wherein the preparation results in proliferation of CD3+-specific immune cells in the person, wherein administration of the preparation results in the proliferation of CD3+/CD4+-specific immune cells (helper cells) in the person, wherein administration of the preparation results in proliferation of CD3-/CD16,56+-specific immune cells (natural killer cells) in the person, wherein administration of the preparation results in proliferation of CD4+/CD8+-specific immune cells (suppressor cells) in the person. Furthermore, no working examples are provided that demonstrate the efficacy of reducing blood cholesterol concentration in the person, in reducing low-density lipoprotein (LDL) concentration, in reducing the probability of atherosclerosis, wherein administration of the preparation results in proliferation of T-lymphocytes in the person, wherein administration of the preparation results in proliferation of CD3+-specific immune cells in the person, wherein administration of the preparation results in

the proliferation of CD3+/CD4+-specific immune cells (helper cells, wherein administration of the preparation results in proliferation of CD3-/CD16,56+-specific immune cells (natural killer cells), and wherein administration of the preparation results in proliferation of CD4+/CD8+-specific immune cells.

Predictability and State of the Art: The state of the art at the time the invention was made was unpredictable and underdeveloped. For example, Furmanowa et al. (U, Planta Med. 2001; 67: 146-149) teaches that *Withania somnifera* plantlets were produced *in vitro* from the shoot-tip of aseptically germinated seedlings under various conditions, that the plant material was extracted with methanol, that withaferin A was isolated from leaves of *Withania somnifera*, that immunosuppressive activity of *Withania somnifera* samples was evalutated using an *in vitro* lymphocyte proliferation assay using mice splenocytes and that T-cell response was measured in response to T cell receptor (CD3) ligation using an anti-CD3 antibody and B cell mitogenic response was evaluated in response to bacterial lipopolysaccharide (*E. coli*) (See Abstract and page 147 "Materials and Methods"). Furmanowa further teaches that results show that while the methanolic extract prepared from the leaves of tissue culture grown plantlets had no immunomodulatory activity, the similar extract from those plantlets transferred to greenhouse showed significant immunosuppressive effects and that HPLC analysis showed the presence of withaferine A in both samples (See page 149, "Evaluation of Immunomodulatory Activity"). Thus, while the claim-designated method may be useful for providing such an effect, Applicant does not disclose a method comprising: obtaining any or all types of agents prepared from any or all types of plant seedlings enriched with

electrolytes comprised in a pharmaceutical preparation; and administering the preparation to a person; wherein administration of the preparation results in reduction of blood cholesterol concentration in the person, wherein administration of the preparation results in the reduction of low-density lipoprotein (LDL) concentration in the person, wherein administration of the preparation results in a reduced probability of atherosclerosis, wherein administration of the preparation results in proliferation of T-lymphocytes in the person, wherein the preparation results in proliferation of CD3+-specific immune cells in the person, wherein administration of the preparation results in the proliferation of CD3+/CD4+-specific immune cells (helper cells) in the person, wherein administration of the preparation results in proliferation of CD3-/CD16,56+-specific immune cells (natural killer cells) in the person, wherein administration of the preparation results in proliferation of CD4+/CD8+-specific immune cells (suppressor cells) in the person. The Office further notes that while the specification discloses that the claim-designated methods and claim designated compositions will have utility in humans in reducing blood cholesterol concentration in the person, in reducing low-density lipoprotein (LDL) concentration, in reducing the probability of atherosclerosis, wherein administration of the preparation results in proliferation of T-lymphocytes in the person, wherein administration of the preparation results in proliferation of CD3+-specific immune cells in the person, wherein administration of the preparation results in the proliferation of CD3+/CD4+-specific immune cells (helper cells, wherein administration of the preparation results in proliferation of CD3-/CD16,56+-specific immune cells (natural killer cells), and wherein administration of the preparation results

in proliferation of CD4+/CD8+-specific immune cells, nowhere in the specification or in the limitations does Applicant direct the claimed subject matter to the administration of compositions comprising any or all types of agents prepared from any or all types of plant seedlings enriched with electrolytes comprised in a pharmaceutical preparation to any subject.

Please note that the state of the art that is cited herein is made based upon what the Examiner believes Applicant appears to be claiming. Since the disclosure is ambiguous, it is hard to tell exactly if Applicant is claiming these ingredients, however, it is clear that Applicant is not enabled nor does Applicant have written description (See above) for the composition as claimed.

It should be noted that at the time of filing of the present application, the art of medicine did not recognize the administration of compositions comprising any or all types of agents prepared from any or all types of plant seedlings enriched with electrolytes comprised in a pharmaceutical preparation for reducing low-density lipoprotein (LDL) concentration, in reducing the probability of atherosclerosis, wherein administration of the preparation results in proliferation of T-lymphocytes in the person, wherein administration of the preparation results in proliferation of CD3+-specific immune cells in the person, wherein administration of the preparation results in the proliferation of CD3+/CD4+-specific immune cells (helper cells, wherein administration of the preparation results in proliferation of CD3-/CD16,56+-specific immune cells (natural killer cells), and wherein administration of the preparation results in proliferation of CD4+/CD8+-specific immune cells comprising the step of administering compositions

comprising any or all types of agents prepared from any or all types of plant seedlings enriched with electrolytes comprised in a pharmaceutical preparation, wherein said compositions comprising any or all types of agents prepared from any or all types of plant seedlings enriched with electrolytes comprised in a pharmaceutical preparation reduce blood cholesterol concentration, to reduce low-density lipoprotein (LDL) concentration, to reduce the probability of atherosclerosis, wherein administration of the preparation results in proliferation of T-lymphocytes, wherein administration of the preparation results in proliferation of CD3+-specific immune cells, wherein administration of the preparation results in the proliferation of CD3+/CD4+-specific immune cells (helper cells, wherein administration of the preparation results in proliferation of CD3-/CD16,56+-specific immune cells (natural killer cells), and wherein administration of the preparation results in proliferation of CD4+/CD8+-specific immune cells in humans.

Amount of Experimentation Necessary: The quantity of experimentation necessary to carry out the claimed invention is high, as the skilled artisan could not rely on the prior art or instant specification to teach how to make and use any or all types of agents prepared from any or all types of plant seedlings enriched with electrolytes comprised in a pharmaceutical preparation for reducing low-density lipoprotein (LDL) concentration, in reducing the probability of atherosclerosis, wherein administration of the preparation results in proliferation of T-lymphocytes in the person, wherein administration of the preparation results in proliferation of CD3+-specific immune cells in the person, wherein administration of the preparation results in the proliferation of

CD3+/CD4+-specific immune cells (helper cells, wherein administration of the preparation results in proliferation of CD3-/CD16,56+-specific immune cells (natural killer cells), and wherein administration of the preparation results in proliferation of CD4+/CD8+-specific immune cells comprising the step of administering compositions comprising any or all types of agents prepared from any or all types of plant seedlings enriched with electrolytes comprised in a pharmaceutical preparation, wherein said compositions comprising any or all types of agents prepared from any or all types of plant seedlings enriched with electrolytes comprised in a pharmaceutical preparation reduce blood cholesterol concentration, to reduce low-density lipoprotein (LDL) concentration, to reduce the probability of atherosclerosis, wherein administration of the preparation results in proliferation of T-lymphocytes, wherein administration of the preparation results in proliferation of CD3+-specific immune cells, wherein administration of the preparation results in the proliferation of CD3+/CD4+-specific immune cells (helper cells, wherein administration of the preparation results in proliferation of CD3-/CD16,56+-specific immune cells (natural killer cells), and wherein administration of the preparation results in proliferation of CD4+/CD8+-specific immune cells in humans. In order to carry out the claimed invention, one of ordinary skill in the art would have to identify compositions comprising any or all types of agents prepared from any or all types of plant seedlings enriched with electrolytes comprised in a pharmaceutical preparation that can be administered in a therapeutically effective dose with an acceptable level of side-effects.

In view of the breadth of the claims and the lack of guidance provided by the

specification as well as the unpredictability of the art, the skilled artisan would have required an undue amount of experimentation to make and/or use the claimed invention. Therefore, Claims 25-35 are not considered to be fully enabled by the instant specification.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 25-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The metes and bounds of Claim 25 are rendered uncertain by the phrase "obtaining an agent prepared from plant seedlings enriched with electrolytes comprised in a pharmaceutical preparation" in claim 25, lines 2 and 3 because it is unclear if Applicant means that an agent is made of plant seedlings that have been enriched with electrolytes or if Applicant means an agent is made of plant seedlings and the plant seedlings are then combined with electrolytes to provide a pharmaceutical preparation or if Applicant means a specific compound is extracted from plant seedlings, wherein the plant seedlings have been grown in an abundance of electrolytes or if Applicant means a specific compound extracted from plant seedlings is then combined with electrolytes to form a pharmaceutical preparation or if Applicant means an agent (either extracted from plant seedlings or plant seedlings themselves as an agent) is enriched with electrolytes. The lack of clarity renders the claims indefinite since the resulting

claims do not clearly set forth the metes and bounds of the patent protection desired.

Please note that no art rejection has currently been made because the claims are so unclear and incomprehensible that a proper art search could not be performed. The fact that no art rejection has been made does not indicate that no art exists or that the claims would be allowable if Applicant were to overcome the rejections above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy L. Clark whose telephone number is (571) 272-1310. The examiner can normally be reached on 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Amy L. Clark
AU 1655

Amy L. Clark
April 27, 2007

MICHELE FLOOD
PRIMARY EXAMINER